



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFA-305

Ms. Anne M. Boone
Mr. Charles C. Nelson
638 1st St.
Helena, MT 59601

JUL 13 1999

Food and Drug Administration
Rockville MD 20857

0363 '99 JUL 16 09:52

Dear Ms. Boone and Mr. Nelson:

This is in response to your letter dated June 29, 1999, concerning the use of recombinant Bovine Growth Hormone (rBGH) in dairy cows.

Thank you for sharing your concerns on this issue. The use of drugs in livestock and poultry is strictly regulated. Before any drug intended for use in animals is approved, it must undergo extensive chemical and toxicological testing which must demonstrate that the food from these animals is safe for human consumption.

Bovine somatotropin (bST) was approved by the Food and Drug Administration (FDA) in 1993. The recombinant, or genetically engineered form of bST (rbST) is virtually identical to a cow's natural somatotropin, a hormone produced in its own pituitary gland that stimulates milk production. Since bST is a protein-based hormone, rbST is broken down during digestion, which makes it biologically inactive and incapable of having any effect in humans or animals. Over 120 studies were reviewed by FDA scientists that examined the safety of milk and meat from dairy cows treated with rbST. They concluded that there was no increased health risk to consumers.

I am enclosing materials which provide further information concerning this matter. In addition, I am forwarding your letter to Dockets Management Branch for inclusion in Docket Number 98P-1194 -- Withdrawal of NADA Approval for Posilac -- rBGH. Please visit our Internet Home Page at <http://www.fda.gov/cvm>.

Sincerely yours,

Karen A. Kandra

Karen A. Kandra
Consumer Safety Officer
Center for Veterinary Medicine

Enclosures

98P-1194

A
C 184 /ANS

6-29-99

FDA
200 C St SW
Wash DC 20204

Hello -

Why or why is rBGH continuing to be approved? Why can't Cows just be allowed to do their natural cow thing.

Why the push to produce bigger, prettier, more? Come down to more money for the producer.

What about the health of not only these producers but of the general public? You folks eat & drink too. Don't you ever worry (really) about the long term effects of what you approve?

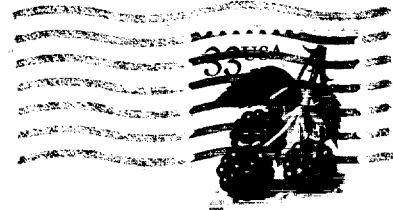
Think again. Ben rBGH.

Dynne M Boone

Charles C Nelson

638 1st St- Helena MT 59601

Booke / Nelson
638 / ST ST
Helena MT 59601



FDA
200 C ST SW
Wash DC 20204

HF624